PCT

WORLD INTELLECTUAL PROPERTY ORGANIZATION
International Bureau

INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification 7 :
A61M 5/46, 5/32

A1

(11) International Publication Number: WO 00/56384

(43) International Publication Date: 28 September 2000 (28.09.00)

(21) International Application Number: PCT/IB00/00289

(22) International Filing Date: 17 March 2000 (17.03.00)

(30) Priority Data:
99/2217 19 March 1999 (19.03.99) ZA

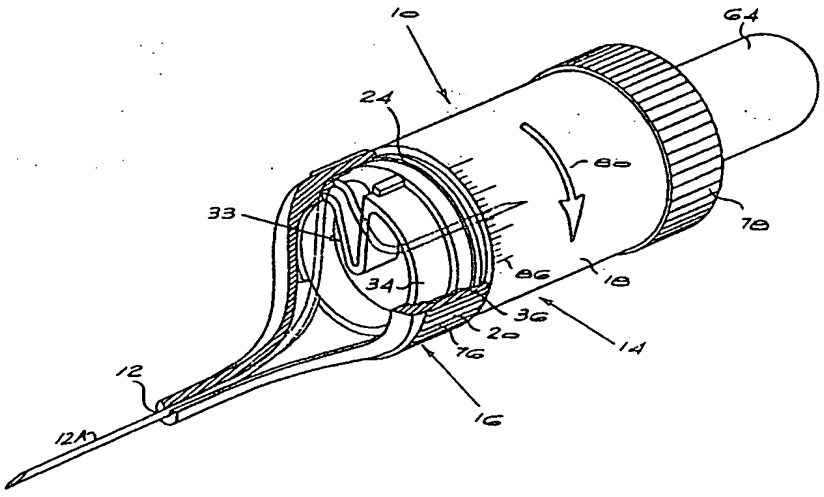
(71)(72) Applicants and Inventors: DUGMORE, Peter, Balfour [ZA/ZA]; 4 Swanmore Road, Rondebosch, 7700 Cape Town (ZA). BULL, Anthony, Eric [ZA/ZA]; 31 Grotto Road, Rondebosch, 7700 Cape Town (ZA). REYNOLDS, Stanford, William, Gladwin [ZA/ZA]; 18 Hopson Road, 3630 Westville (ZA).

(74) Agents: GILSON, David, Grant et al.; Spoor and Fisher, Rochester Place, 173 Rivonia Road, Morningside, Sandton, P.O. Box 41312, 2024 Craighall (ZA).

(81) Designated States: AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CR, CU, CZ, DE, DK, DM, DZ, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, TZ, UA, UG, US, UZ, VN, YU, ZA, ZW, ARIPO patent (GH, GM, KE, LS, MW, SD, SL, SZ, TZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG).

Published
With international search report.

(54) Title: AN ADJUSTABLE NEEDLE ASSEMBLY



(57) Abstract

An adjustable and retractable needle assembly (10) comprises a deformable hollow needle (12) and a two–part needle housing (14) having a front spigot component (16) and a rear barrel or shield component (18) which are rotatably mounted to one another. The spigot component (16) includes a laterally offset spigot (26) having a guide passage (28) defined therein through which the needle (12) is able to slide. A capstan arrangement (33) extends from the front end of the barrel, and includes a take–up spool (34), with an annular gap (36) being defined between the inner surface (38) of the skirt (20) and the outer surface of the spool (34). The needle (12) is deformed laterally off the axis (30) of the guide passage (28) about a curved interface (48). Counter–clockwise rotation of the barrel (18) relative to the offset spigot causes the needle progressively to wrap around the outer surface of the spool (34) within the gap (36) until the sharp end of the needle is completely retracted into a safe position within the guide aperture (28).

FOR THE PURPOSES OF INFORMATION ONLY

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

AL	Albania	ES	Spain	LS	Lesotho	SI	Slovenia
AM	Armenia	FI	Finland	LT	Lithuania	SK	Slovakia
AT	Austria	FR	France	LU	Luxembourg	SN	Senegal
AU	Australia	GA	Gabon	LV	Latvia	SZ	Swaziland
AZ	Azerbaijan	GB	United Kingdom	MC	Monaco	TD	Chad
BA	Bosnia and Herzegovina	GE	Georgia	MD	Republic of Moldova	TG	Togo
BB	Barbados	GH	Ghana	MG	Madagascar	TJ	Tajikistan
BE	Belgium	GN	Guinea	MK	The former Yugoslav Republic of Macedonia	TM	Turkmenistan
BF	Burkina Faso	GR	Greece			TR	Turkey
BG	Bulgaria	HU	Hungary	ML	Mali	TT	Trinidad and Tobago
BJ	Benin	IE	Ireland	MN	Mongolia	UA	Ukraine
BR	Brazil	IL	Israel	MR	Mauritania	UG	Uganda
BY	Belarus	IS	Iceland	MW	Malawi	US	United States of America
CA	Canada	IT	Italy	MX	Mexico	UZ	Uzbekistan
CF	Central African Republic	JP	Japan	NE	Niger	VN	Viet Nam
CG	Congo	KE	Kenya	NL	Netherlands	YU	Yugoslavia
CH	Switzerland	KG	Kyrgyzstan	NO	Norway	ZW	Zimbabwe
CI	Côte d'Ivoire	KP	Democratic People's Republic of Korea	NZ	New Zealand		
CM	Cameroon			PL	Poland		
CN	China	KR	Republic of Korea	PT	Portugal		
CU	Cuba	KZ	Kazakstan	RO	Romania		
CZ	Czech Republic	LC	Saint Lucia	RU	Russian Federation		
DE	Germany	LI	Liechtenstein	SD	Sudan		
DK	Denmark	LK	Sri Lanka	SE	Sweden		
EE	Estonia	LR	Liberia	SG	Singapore		

AN ADJUSTABLE NEEDLE ASSEMBLY

BACKGROUND OF THE INVENTION

THIS invention relates to an adjustable needle assembly, and in particular to an adjustable needle assembly for use in phlebotomy or blood collection procedures.

There are various different types of blood collecting assemblies currently available on the market. A typical assembly includes a double pointed needle having a central threaded needle boss which engages a complementally threaded socket defined at the front end of a needle holder. The needle holder is in turn formed with a barrel or shield having a rear open end for receiving a vacuum phial. A front protective sheath is fitted over the front pointed end of the needle, and a rear rubber teat fits over the rear pointed end of the needle. The rubber teat is in turn covered with a rigid rear protective sheath.

Needle lengths vary, depending on the patient and the procedure. For instance, a far shorter needle may be used when extracting blood from a child as opposed to an adult. As a result, large stocks of differing needle lengths need to be provided. Phlebotomy needles are also relatively expensive, in that a specially threaded hub needs to be moulded and bonded to the centre of the double-pointed needle and both front and rear protective sheaths are required to protect both ends of the needle.

Needle-stick is not confined to in-use scenarios, but is also prevalent in disposal and post-disposal situations. A number of prior art devices rely on the replacement of protective needle sheaths after the hypodermic procedure. The replacement exercise in itself often involves the risk of needle-stick. There

is a danger of the needle sheath subsequently working loose and being displaced, and disposal personnel being placed at risk. In addition, provision of both front and rear protective needle sheaths adds to both material and manufacturing costs.

Current technology offering needle-safe alternatives generally relies on extended barrel length or supplemental barrel shields to allow the retraction of the needle point to a safe position. This inevitably results in an increase in material requirements and bulk of the disposed article, with associated increases in difficulty of handling and cost.

SUMMARY OF THE INVENTION

According to the invention there is provided an adjustable needle assembly comprising a needle housing, a first needle guide passage defined in a front end of the housing, a needle that is axially slidable within the passage, and needle length adjusting means, wherein the guide passage defines a central guide axis, and the needle length adjusting means is arranged to deviate the needle laterally relative to the guide axis to adjust the distance that the needle projects from the housing.

In a preferred form of the invention, the needle is retractable by the needle length adjusting means from an extended position in which a point of the needle projects an administrable distance from the housing to a retracted safe position in which the needle point is retracted within the housing.

Advantageously, the needle length adjusting means comprises needle take-up means carried on the housing for taking up a length of the needle, the take-up means typically comprising a rotatable capstan arrangement for winding or wrapping up a length of the needle.

Conveniently, the needle assembly includes indexed ratcheting means for controlling progressive retraction of the needle into the housing and essentially preventing subsequent extension of the needle.

Typically, the needle is a hollow hypodermic needle of unitary construction, and is not fitted with a needle seat.

In one preferred form of the invention, the needle is a double-pointed needle having a second rear pointed end for penetrating a fluid collection phial, the housing being formed with a rear phial-receiving opening into which the phial is arranged to be inserted, in which case the needle length adjusting means may be arranged to retract both the front and rear pointed ends of the needle into retracted safe positions within the housing, and a second rearwardly extending needle guide passage is defined in the housing for accommodating the rear pointed end of the needle in an axially sliding fit.

Needle locking means may be provided for locking the needle in the extended position.

In one form of the invention, the needle locking means may comprise a kinked or cranked portion of the needle and a complemental guide defined within the needle length adjusting means for seating the kinked or cranked portion of the needle.

The needle locking means may alternatively include needle clamping means carried on the needle length adjusting means for clamping an essentially rectilinear portion of the needle when in the extended position.

The first needle guide passage may be defined by a front spigot formation extending from a front end of the housing, the housing being round cylindrical

in form, and the spigot being offset from a central axis of the housing, with the axis of the guide passage being parallel to the housing axis.

In one form of the invention, the capstan arrangement is arranged to rotate about an axis which is substantially parallel to the central axis of the guide passage, the axis of rotation also being substantially coaxial with a central axis of the housing.

In this form of the invention, the housing may comprise a front offset spigot component defining the first needle guide passage and a rear barrel component which is rotatably mounted to the spigot component, the capstan arrangement including a take-up spool defined towards a front end of the barrel component, and a complemental skirt extending rearwardly from the spigot component, with an annular needle guide passage being defined between the skirt and the spool within which the needle may be wrapped on rotation of the barrel component relative to the spigot component about a common central axis.

In an alternative form of the invention, the capstan arrangement is arranged to rotate about an axis which extends transversely relative to the central axis of the guide passage and housing.

The capstan arrangement may accordingly comprise at least one take-up spool carried on a shaft which is journalled to the housing, and on which is carried a thumbwheel.

In one form of the invention, the capstan assembly may be slidable within the housing to which it is mounted via an indexing arrangement for allowing the protruding length of the needle initially to be bi-directionally adjusted without deforming the needle.

In an alternative form of the invention, the needle length adjusting means comprises a capstan arrangement including a pair of cammed take-up spools separated by a central passage through which the needle passes, the take-up spools being carried on a shaft which is journalled to the housing, with rotation of the shaft causing the needle to wrap in opposite directions about cammed outer faces of the spools so as simultaneously to retract the front and rear pointed ends of the needle into a safe position within the housing.

In a still further alternative form of the invention, the housing comprises a front offset spigot component defining the first needle guide passage and a rear barrel component which is rotatably mounted to the spigot component, the needle length adjusting means including a dual capstan assembly comprising a front rotary capstan component mounted rotatably between the front spigot component and the rear barrel component, and a rear capstan formation located at a front end of the barrel component, the retractable needle assembly further comprising first ratcheting means for allowing for tandem rotation of the front rotary capstan component and the barrel component relative to the front spigot component for enabling the front portion of the needle to be retracted by winding it around one of the take-up spools, and second ratcheting means for enabling the capstan component to rotate in the opposite direction in tandem with the front spigot component relative to the barrel component for enabling the rear portion of the needle to be taken up about the rear capstan formation.

BRIEF DESCRIPTION OF THE DRAWINGS

Figure 1 shows a partly cutaway perspective view of a first embodiment of an adjustable needle assembly of the invention;

Figures 2A to 2C show cross-sectional side views of the adjustable needle assembly of Figure 1 illustrating the steps involved in moving the needle from an extended to a retracted position;

Figures 3A to 3C show corresponding partly cutaway end-on views corresponding to the cross-sectional side views of Figures 2A to 2C;

Figures 4A & 4B show cross-sectional underplan views of a second embodiment of an adjustable needle assembly in the fully extended and partly retracted positions;

Figure 5 shows a partly cross-sectional side view of the adjustable needle assembly of Figure 4B in the partly retracted position;

Figures 6A & 6B show respective partly cross-sectional side and top plan views of a third embodiment of an adjustable needle assembly in the extended position;

Figure 7 shows a partly cross-sectional side view of a fourth embodiment of an adjustable needle assembly of the invention in an extended position;

Figure 8 shows a partly cross-sectional top plan view of the adjustable needle assembly of Figure 7 in an intermediate retracted position;

Figure 9 shows a cross-sectional side view of a fifth embodiment of an adjustable needle assembly in an extended position;

Figure 10 shows an end-on view of a front rotary capstan component forming part of the adjustable needle assembly of Figure 9;

Figure 11 shows an end-on view of a rear capstan formation and barrel forming part of the adjustable needle assembly of Figure 9; and

Figure 12 shows a partly cutaway exploded perspective view of the fifth embodiment of the adjustable needle assembly of Figures 9 to 11.

DESCRIPTION OF EMBODIMENTS

Referring first to Figures 1, 2A and 3A, an adjustable and retractable needle assembly 10 comprises a deformable hollow 21 gauge needle 12 formed from surgical-grade steel and a needle housing 14. The needle housing 14 is a two-part housing, having a front spigot component 16 and a rear barrel or shield component 18. The spigot component 16 is formed with a knurled skirt 20 which is rotatably mounted to the barrel component 18 via an inner circumferential recess 22 which forms a snug rotational fit with a complemental outer peripheral rib 24 defined towards the front end of the barrel. The spigot component 16 includes a laterally offset spigot 26 having a guide aperture 28 defined therein within which the needle 12 is able to slide in a snug yet sliding fit. The guide aperture 28 defines a rectilinear central axis 30, with a point 31

of the needle being colinear with the axis 30. Prior to use, the needle is provided with a needle sheath 32 which fits over a front end of the spigot 26.

A capstan arrangement 33 extends from the front end of the barrel, and includes a take-up spool 34. An annular gap 36 is defined between the inner surface 38 of the skirt 20 and the outer surface of the spool 34. The spool 34 is formed with a V-shaped indent 40, having radially extending walls 40A and 40B. The radial wall 40B terminates in a pawl 44, which co-operates with a series of sawtooth ratchet formations 46 on the inner surface of the skirt to provide stepwise unidirectional rotation of the skirt 20 relative to the barrel 18.

The needle 12 is deformed or deviated laterally off the axis 30 about a curved interface 48 defined between the radial wall 40A and the outer circular wall 34 of the turret, the radius of which is greater than the kink radius of the needle. Thereafter, a cranked radial portion 50 of the needle extends inwardly to the centre 49 of the turret, from where it extends rearwardly and axially through a central axial guide aperture 52 defined in a rear spigot 54, and terminates in a pointed end 56. The pointed end is covered with a rubber teat 58 which is fitted to the rear end of the spigot 54. The radius of the curved interface 60 between the base wall 62 of the turret and the spigot aperture 52 is similarly greater than the maximum kink radius of the needle 12.

The blood sampling procedure is initiated by removal of the needle sheath 32, and optionally adjusting the protruding end of the needle to the desired length. This is achieved by one-way rotation of the barrel in click-stop increments determined by the co-operating pawl 44 and ratchet formations 46. Each click of the pawl over a ratchet sawtooth in this embodiment gives a tactile indication of approximately 5mm reduction in the length of the needle.

The sharp front end 31 of the needle is then inserted into a vein. The offset spigot 26 facilitates the tangential insertion of the needle into a surface vein to

any desired depth. After the needle has been inserted, a conventional vacuum phial 64 is inserted through a rear opening 66 defined in the barrel 18. A recessed front face 68 of a rubber stopper 70 is brought to bear against the free end of the teat 58, causing the sharp end 56 of the needle to pierce the teat 58 and the stopper 70, with the teat 58 adopting a resilient concertina'd configuration within the recess 68, as is indicated at 72. The pointed end 56 of the needle is in direct communication with the vacuum chamber 74 defined within the phial, resulting in blood being drawn from the vein into the phial 64 via the needle 12.

Removal of the phial 64 from the barrel 18 results in the resealing of the aperture pierced by the rear end 56 of the needle in the rubber teat 58 as the rubber teat springs back into the extended position. Successive phials may be used in a similar repetitive fashion to take as many blood samples as may be required.

Once the desired number of vacuum phials have been filled, the protruding portion 12A of the needle is withdrawn from the vein. The needle is then rendered safe. This is achieved, with the needle point 31 directed away from the practitioner, by gripping in one hand finger grips 76 on the skirt 20, and gripping in the other hand finger grips 78 formed at the base of the barrel 18. The barrel 18 is then rotated in a counter-clockwise direction indicated by arrow 80, when viewed from the rear end of the retractable needle assembly. Rotation of the barrel relative to the spigot portion causes the needle progressively to wrap around the outer surface of the spool 34 in the manner illustrated in Figures 2B and 3B and 2C and 3C, in which incremental wrapped portions 82 and 84 of the needle are illustrated. In the Figure 3C position, the sharp end 31 of the needle is completely retracted into a safe position within the guide aperture 28. In the case of a needle extended by 25mm full retraction of the needle 12 is achieved in this embodiment by rotating the

barrel 18 through approximately 180°, representing five "clicks" of the ratchet formations 46 over the pawl 44.

It will be appreciated that, in the case of blood having to be collected from a child, the length of the needle may initially be further shortened, say, to the Figures 2B and 3B position, in which the needle protrudes a desired distance d. Owing to the pawl and ratchet arrangement, at most, only nominal incremental forward adjustments may be made, limited to the total distance between adjacent ratchets or sawtooth formations 46. Appropriate graduations 86 may be marked on the barrel, which graduations serve to indicate the degree of twisting required so as to achieve ideal needle lengths for subjects of differing sizes and ages, thereby visibly reinforcing the tactile indication provided by the co-operating pawl and ratchet arrangement..

The protruding length of needle is, for practical purposes, unlimited. For example, the needle could extend for 100mm, in which case two complete turns of ten clicks of the pawl and ratchet arrangement would be required to retract the needle completely.

Referring now to Figures 4A, 4B and 5, a retractable needle assembly 90 is shown having a barrel 92 with an integral centrally located spigot 94 defining a guide passage 95 within which a needle 96 is axially moveable. A capstan arrangement 98 includes a rotary shaft 100 journalled for rotation within complemental apertures 102 and 104. A serrated thumbwheel 106 is used manually to rotate the capstan arrangement 98, and a series of sawtooth ratchet formations 108 on the undersurface of the thumbwheel co-operate with complemental sawtooth ratchet formations on the barrel (not shown) to ensure that the thumbwheel can only be rotated in the clockwise direction of arrow 110. The shaft is formed with a pair of cammed take-up spools 112 and 114 which define a central passage 115 through which the rectilinear needle 96 passes when in the Figure 4A position. In this position, the needle is locked by

virtue of the frictional engagement between the needle and the cammed spools where the thumbwheel is rotated to the extent that the cammed spools frictionally engage, but do not deform the needle.

Referring now to Figures 4B and 5, it can clearly be seen how subsequent rotation of the capstan arrangement 98 causes the needle to wrap around the cammed faces 112A and 114A of the respective cammed take-up spools. This has the effect of simultaneously retracting the front and rear needle points 116 and 118 into a safe position. It will be appreciated that Figure 4B illustrates an intermediate position, and that the safe position involves additional wrapping of the needle around the cammed spools until the front needle point 116 is retracted into the spigot 94.

Referring now to Figures 6A and 6B, a third embodiment of a retractable needle assembly 120 is shown which is formed with an offset spigot 122 and a needle 124 which is cranked rather than rectilinear when in the locked extended position, as is the case with the first embodiment. A capstan arrangement 126 is similar to the capstan arrangement 98, save that it is provided with a pair of cammed spools 128 and 130, which, when in the locked position, define a central diametral passage 132 which runs at right angles to the main axis of the needle 124. It is clear that rotation of the thumbwheel 106 will cause the needle to wrap around the outer substantially semi-circular faces 128A and 130A of the respective cammed spools so as to simultaneously retract the opposed needle points 116 and 118.

In Figures 7 and 8, a still further embodiment of a retractable needle assembly 134 is shown in which a capstan arrangement 136 is journalled to a tubular carriage 137 which is in turn arranged to slide within a needle barrel or housing 138. The capstan arrangement includes a shaft 140 having a neck 141 projecting through a slot 142 which is provided with an appropriately scalloped profile 144 for indexing rearward and forward movement of the carriage 137.

The scalloped slot 142 terminates in a rearmost part enlarged circular captivating recess 145 for enabling the shaft 140 to be fully inserted during assembly. A pair of detents 146 limit rearward movement of the carriage to a prescribed carriage stowage position within an ultimate scalloped detent 147. In this position, the front needle point 116 does not protrude beyond the foremost tip of the spigot 122, thereby avoiding the requirement for a separate needle sheath. By providing a sliding capstan arrangement 136, the overall length L of the protruding portion of the needle 148 can initially be adjusted in an indexed fashion in both directions, depending on the application.

The capstan arrangement 136 is formed with a pair of cammed spools 150 between which the needle 148 passes, with rotation of the thumbwheel 106 retracting both needle points 116 and 118 in the manner previously described. Ratchet formations 152 co-operate with pawled edges 154 and 156 to ensure unidirectional rotation of the capstan arrangement in a clockwise needle disposal direction indicated by arrow 157.

Initial rotation of the thumbwheel in the direction of arrow 157 into a first ratcheted position serves to clamp the needle 148 firmly in the extended position. The resultant elastic deformation of the needle induces a torsional resilience between the journalled capstan arrangement 136 and the needle barrel, which urges the neck 141 into engagement with a selected scalloped detent to prevent sliding of the carriage during usage, thereby avoiding any unwanted variation in needle length until completion of the blood collection phase.

Figures 9 to 12 show a still further embodiment of a retractable needle assembly 158 of the invention which has a similar configuration to that of the first embodiment, save that a two-step wrapping procedure is employed. The assembly includes a front offset spigot component 160, a rear barrel component 162 and a dual capstan assembly comprising a front rotary capstan

component 164 and a rear capstan formation 165 located at the front end of the barrel 162. The rotary capstan component 164 is formed with a pair of front take-up spools 166 and 168, with a cranked portion 170 of the needle 172 extending diametrally between the take-up spools 166 and 168. The outer periphery of the rotary capstan component 164 is formed with a series of sawtooth ratchets 174. The sawtooth ratchets have mutually chamfered sets of faces 174A and 174B. The ratchet faces 174A, in conjunction with the complemental series of female ratchets 175 defined on the inner surface of the skirt 176 of the spigot formation, allow for rotation of the capstan component 164 and the barrel 162 in tandem in the direction of arrow 178 relative to the front spigot component 160.

The ratchet faces 174B in turn co-operate with complemental female sawtooth ratchet formations 180 defined on the inner periphery of a turret formation 182 projecting from a front end of the barrel 162. The ratchet formations 180 lockingly engage the complemental ratchet faces 174B when the barrel is rotated in the direction of arrow 178, thereby ensuring that the capstan component 164 rotates in concert with the barrel 162 relative to the front spigot formation 160. This has the effect of commencing wrapping of the front end of the needle 172 around the outer surface of the take-up spool 166 and subsequently about the outer surface of the take-up spool 168 in the manner illustrated in broken outline at 184A. Take-up of the rear portion of the needle 172 is prevented at this stage by a U-shaped bend 185 in the needle as it passes through a slot 186 in the capstan component 164.

After the front portion of the needle 172 has been completely retracted in this manner, the direction of rotation of the barrel portion 162 is reversed. Subsequent rotation in the direction of arrow 187 will cause the rear portion 188 of the needle to be taken up around a rear take-up spool 190 in the manner illustrated in broken outline at 192. The dual capstan assembly allows for complete wrapping of both front and rear needle points by turning the barrel

portion 162 first in one direction so as to wrap the front end of the needle, and then in the other, to take up the back end. As the rear end of the needle is retracted completely, the barrel 162 may safely be made shorter.

It will be appreciated that needle length adjusting means is not limited to a rotatable capstan arrangement of the type claimed and illustrated, which is either parallel or perpendicular to the central guide axis of the needle or the central axis of the housing. By way of example, a capstan arrangement may be provided which rotates about an axis which is oblique or inclined relative to the central guide axis. The invention further contemplates any type of needle length adjusting means which adjusts, and in particular retracts the needle by way of lateral deviation relative to the guide axis by bending, twisting or laterally moving the needle. For example, a simple slide mechanism could be employed which creates a single laterally extending kink or bend in the needle.

The adjustable needle assembly of the invention has a number of significant advantages over prior art phlebotomy devices. In all of the embodiments, the need for both a fitted needle seat and a rear needle sheath is obviated, and in the case of the sliding capstan embodiment, the need for any needle sheath whatsoever is dispensed with completely. In all of the other non-sliding embodiments, as the needle is retracted within the housing, there is no need to replace a front needle sheath after use, and as a result, at all times during the phlebotomy procedure, the practitioner's fingers are located behind the protruding front sharp end of the needle, thereby significantly reducing the possibility of needle-stick injuries.

In certain embodiments of the invention, both ends of the needle are retractable, rendering the rear needle point completely safe after use as well as allowing the depth of the needle housing to be made shorter than the prescribed conventional precautions against needle stick occasioned by inadvertent insertion of a finger tip.

In prior art devices, different lengths of needle – and by extension needle sheaths - need to be stocked for different procedures and patients. In the present invention, the needle length of a single device requiring just one size of needle sheath may readily be adjusted incrementally to cater for different procedures and patients. This is a particularly cost effective solution, as it reduces the stock of needles and needle sheaths required.

The needle manufacturing procedure is also considerably simplified, as there is no need for threaded needle seats to be bonded onto the needles, or for the needle housings to be formed with complementally threaded needle seat sockets.

The offset needle spigot of the invention is further distinguishable over the majority of prior art phlebotomy devices in which the needle is centralised, with the offset spigot avoiding the need to bend the needle during insertion to achieve tangentiality to the skin surface, and further offering the practitioner the facility of tapering the device *in situ* so as to free both hands while minimizing the trauma involved in inadvertently jogging the needle while it is lodged in the vein.

CLAIMS

1. An adjustable needle assembly comprising a needle housing, a first needle guide passage defined in a front end of the housing, a needle that is axially slidable within the passage, and needle length adjusting means, wherein the guide passage defines a central guide axis, and the needle length adjusting means is arranged to deviate the needle laterally relative to the guide axis to adjust the distance that the needle projects from the housing.

2. An adjustable needle assembly according to claim 1 in which the needle is retractable by the needle length adjusting means from an extended position in which a point of the needle projects an administrable distance from the housing to a retracted safe position in which the needle point is retracted within the housing.

3. An adjustable needle assembly according to either one of the preceding claims 1 or 2 in which the needle length adjusting means comprises needle take-up means carried on the housing for taking up a length of the needle.

4. An adjustable needle assembly according to claim 3 in which the take-up means comprises a rotatable capstan arrangement for winding or wrapping up a length of the needle.

5. An adjustable needle assembly according to any one of the preceding claims which includes indexed ratcheting means for controlling progressive retraction of the needle into the housing and essentially preventing subsequent extension of the needle.

6. An adjustable needle assembly according to any one of the preceding claims in which the needle is a hollow hypodermic needle of unitary construction, and is not fitted with a needle seat.

7. An adjustable needle assembly according to claim 6 in which the needle is a double-pointed needle having a second rear pointed end for penetrating a fluid collection phial, the housing being formed with a rear phial-receiving opening into which the phial is arranged to be inserted.

8. An adjustable needle assembly according to claim 7 in which the needle length adjusting means is arranged to retract both the front and rear pointed ends of the needle into retracted safe positions within the housing, and a second rearwardly extending needle guide passage is defined in the housing for accommodating the rear pointed end of the needle in an axially sliding fit.

9. An adjustable needle assembly according to any one of the preceding claims 6 to 8 which include needle locking means for locking the needle in the extended position.

10. An adjustable needle assembly according to claim 9 in which the needle locking means comprises a kinked or cranked portion of the needle and a complemental guide defined within the needle length adjusting means for seating the kinked or cranked portion of the needle.

11. An adjustable needle assembly according to claim 9 in which the needle locking means includes needle clamping means carried on the needle length adjusting means for clamping an essentially rectilinear portion of the needle when in the extended position.

12. An adjustable needle assembly according to any one of the preceding claims in which the first needle guide passage is defined by a front spigot formation extending from a front end of the housing, the housing being round cylindrical in form, and the spigot being offset from a central axis of the housing, with the axis of the guide passage being parallel to the housing axis.

13. An adjustable needle assembly according to claim 4 in which the capstan arrangement is arranged to rotate about an axis which is substantially parallel to the central axis of the guide passage, the axis of rotation also being substantially coaxial with a central axis of the housing.

14. An adjustable needle assembly according to claim 13 in which the housing comprises a front offset spigot component defining the first needle guide passage and a rear barrel component which is rotatably mounted to the spigot component, the capstan arrangement including a take-up spool defined towards a front end of the barrel component, and a complemental skirt extending rearwardly from the spigot component, with an annular needle guide passage being defined between the skirt and the spool within which the needle may be wrapped on rotation of the barrel component relative to the spigot component about a common central axis.

15. An adjustable needle assembly according to claim 4 in which the capstan arrangement is arranged to rotate about an axis which extends transversely relative to the central axis of the guide passage and housing.

16. An adjustable needle assembly according to claim 15 in which the capstan arrangement comprises at least one take-up spool carried on a

shaft which is journalled to the housing, and on which is carried a thumbwheel.

17. An adjustable needle assembly according to either one of claims 15 or 16 in which the capstan assembly is slidable within the housing to which it is mounted via an indexing arrangement for allowing the protruding length of the needle initially to be bi-directionally adjusted without deforming the needle.

18. An adjustable needle assembly according to claim 8 in which the needle length adjusting means comprises a capstan arrangement including a pair of cammed take-up spools separated by a central passage through which the needle passes, the take-up spools being carried on a shaft which is journalled to the housing, with rotation of the shaft causing the needle to wrap in opposite directions about cammed outer faces of the spools so as simultaneously to retract the front and rear pointed ends of the needle into a safe position within the housing.

19. An adjustable needle assembly according to claim 8 in which the housing comprises a front offset spigot component defining the first needle guide passage and a rear barrel component which is rotatably mounted to the spigot component, the needle length adjusting means including a dual capstan assembly comprising a front rotary capstan component mounted rotatably between the front spigot component and the rear barrel component, and a rear capstan formation located at a front end of the barrel component, the retractable needle assembly further comprising first ratcheting means for allowing for tandem rotation of the front rotary capstan component and the barrel component relative to the front spigot component for enabling the front portion of the needle to be retracted by winding it around one of the take-up spools, and second ratcheting means for enabling the capstan

component to rotate in the opposite direction in tandem with the front spigot component relative to the barrel component for enabling the rear portion of the needle to be taken up about the rear capstan formation.

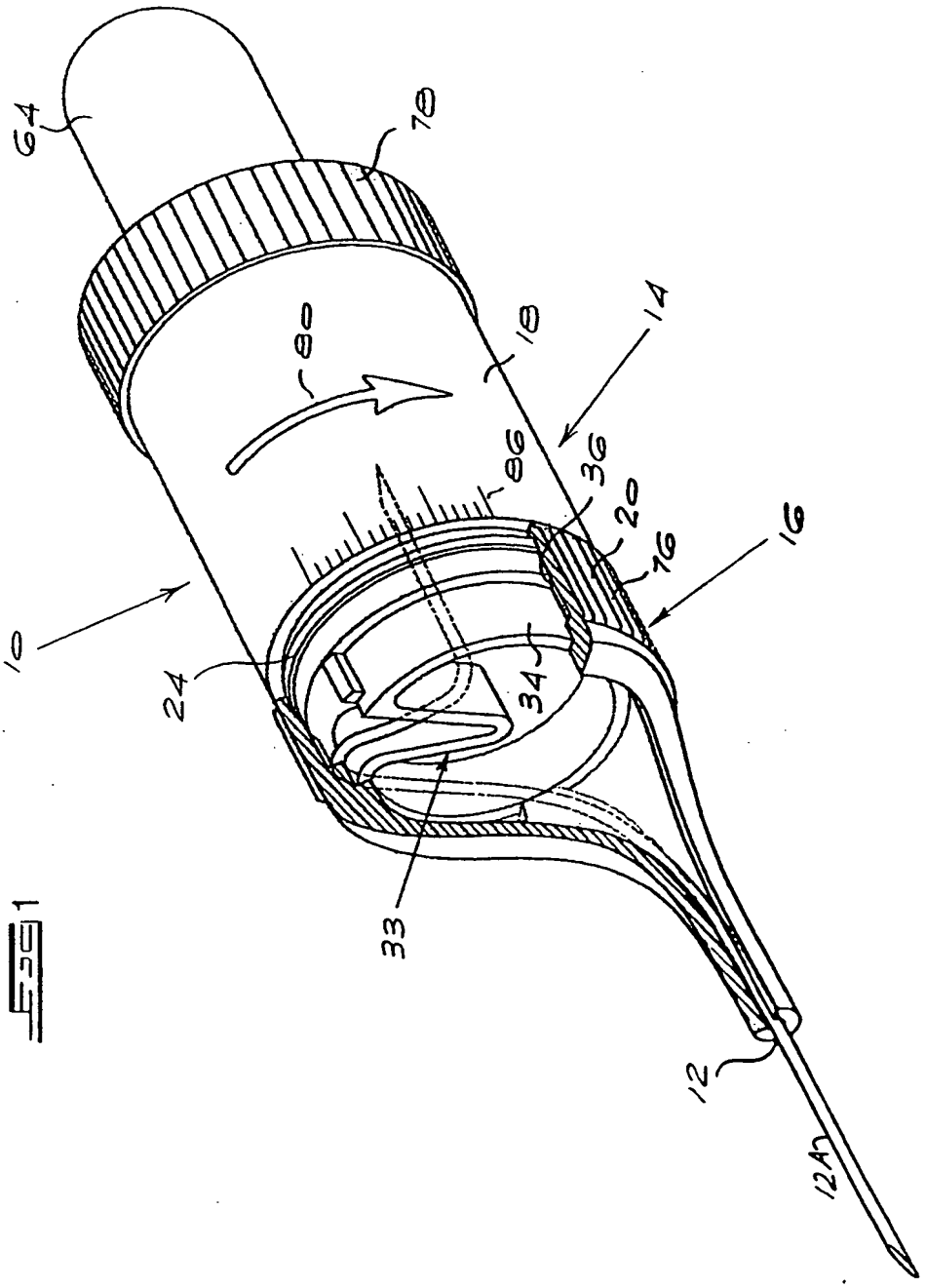
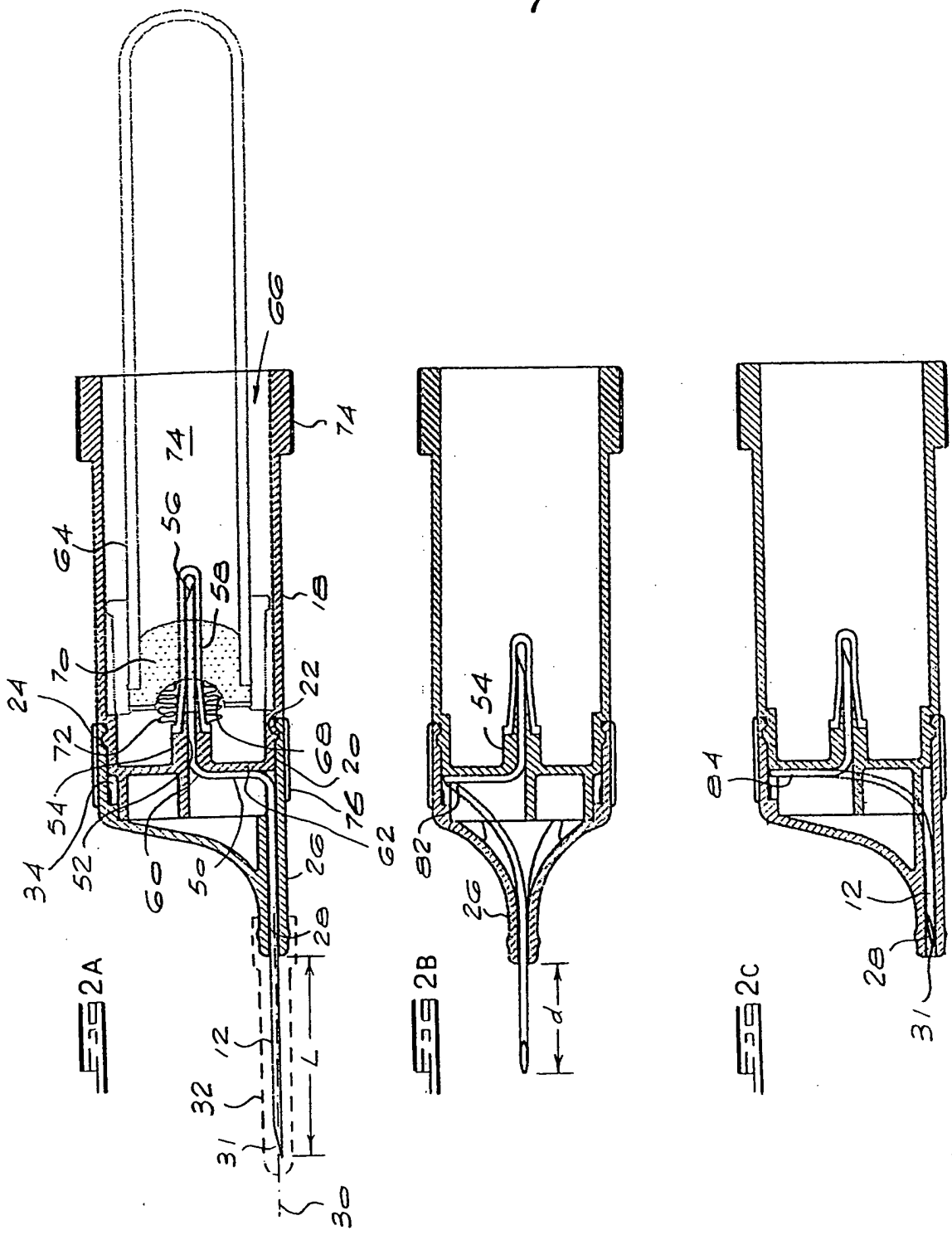


FIG 1


66
74
74
64
56
58
18
24
70
22
72
68
20
54
76
34
52
60
50
62
26
28
12
32
31
L
30
82
54
26
d
84
12
28
31

2A 2B 2C

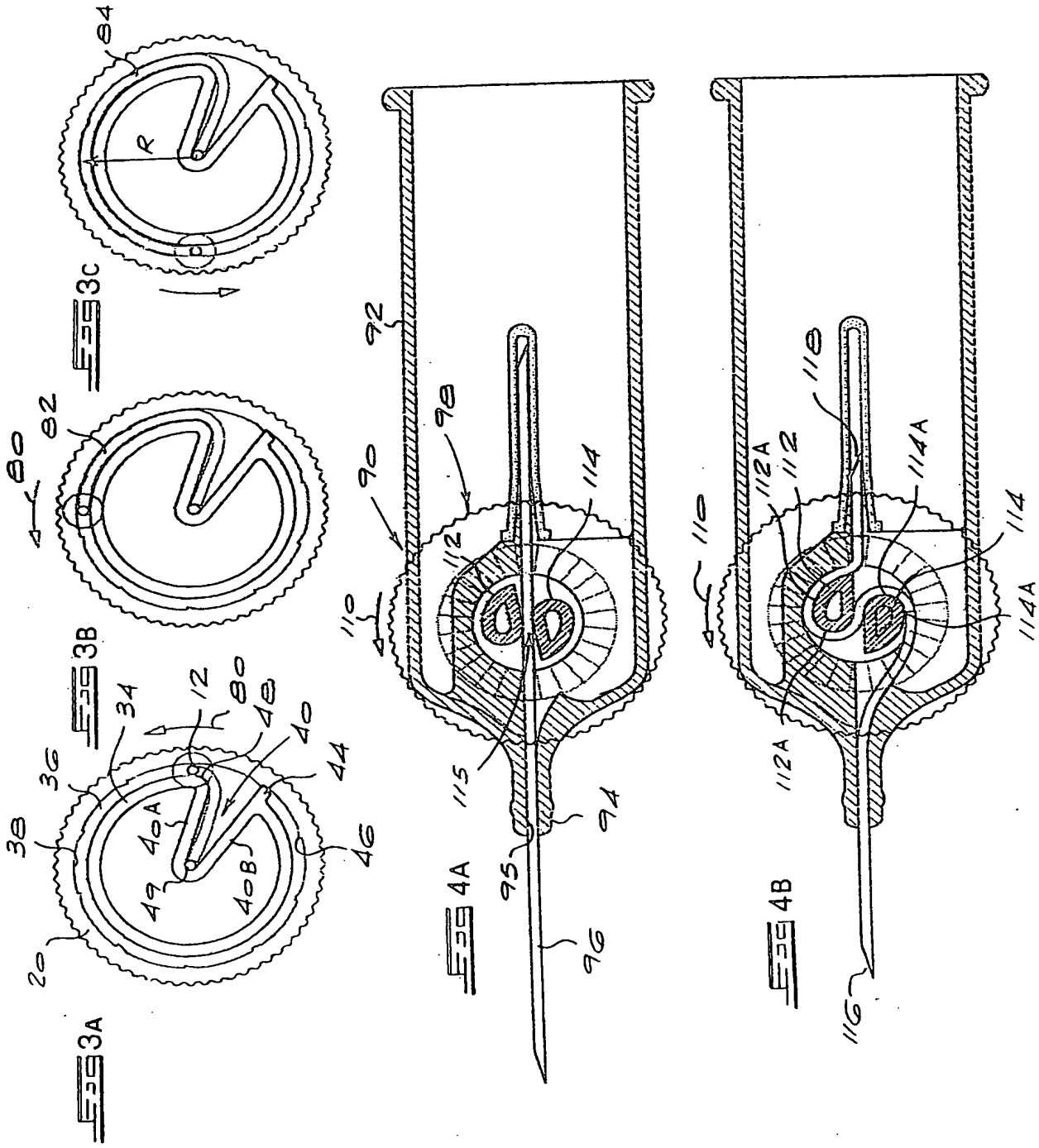


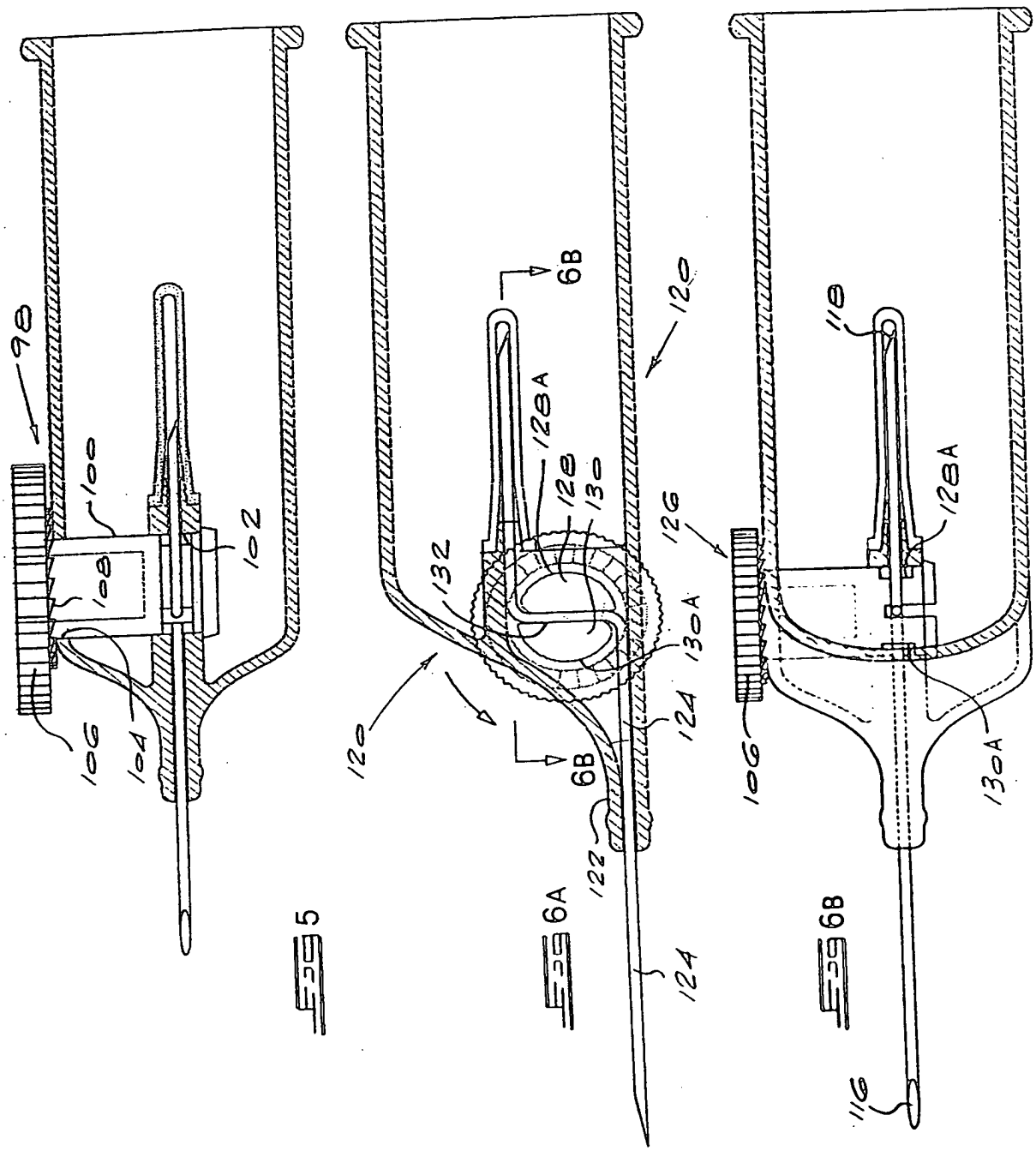
FIG 3C

FIG 3B

FIG 3A

FIG 4A

FIG 4B


98
100
102
108
106
104
5
120
6B
128A
128
130
132
126
130A
124
122
6A
118
116
6B

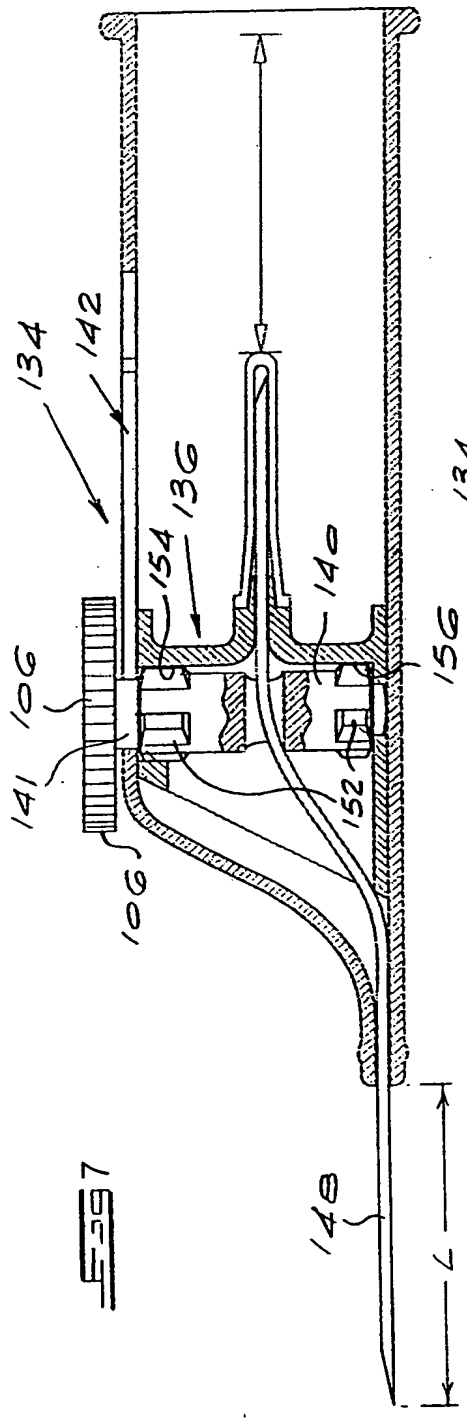

134
142
136
154
140
156
106
141
152
106
148
L

Fig 7

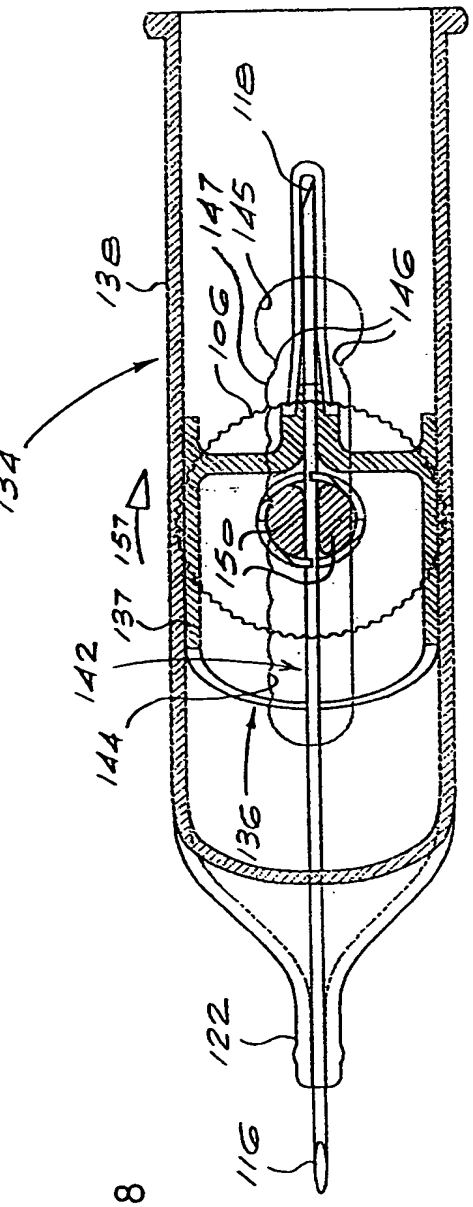

118
147
145
138
106
146
134
157
150
137
142
144
136
122
116

Fig 8

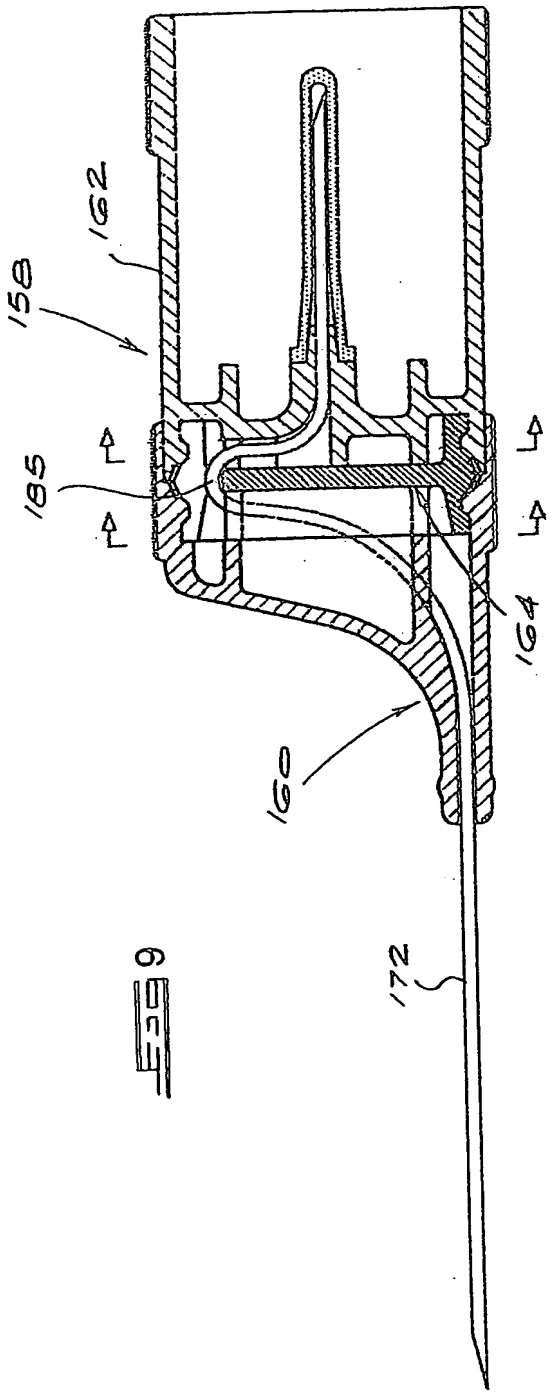


Fig 9

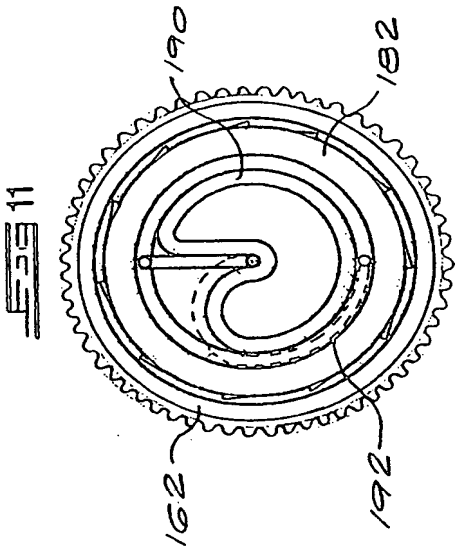


Fig 11

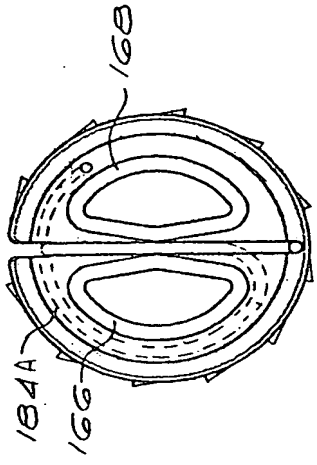


Fig 10

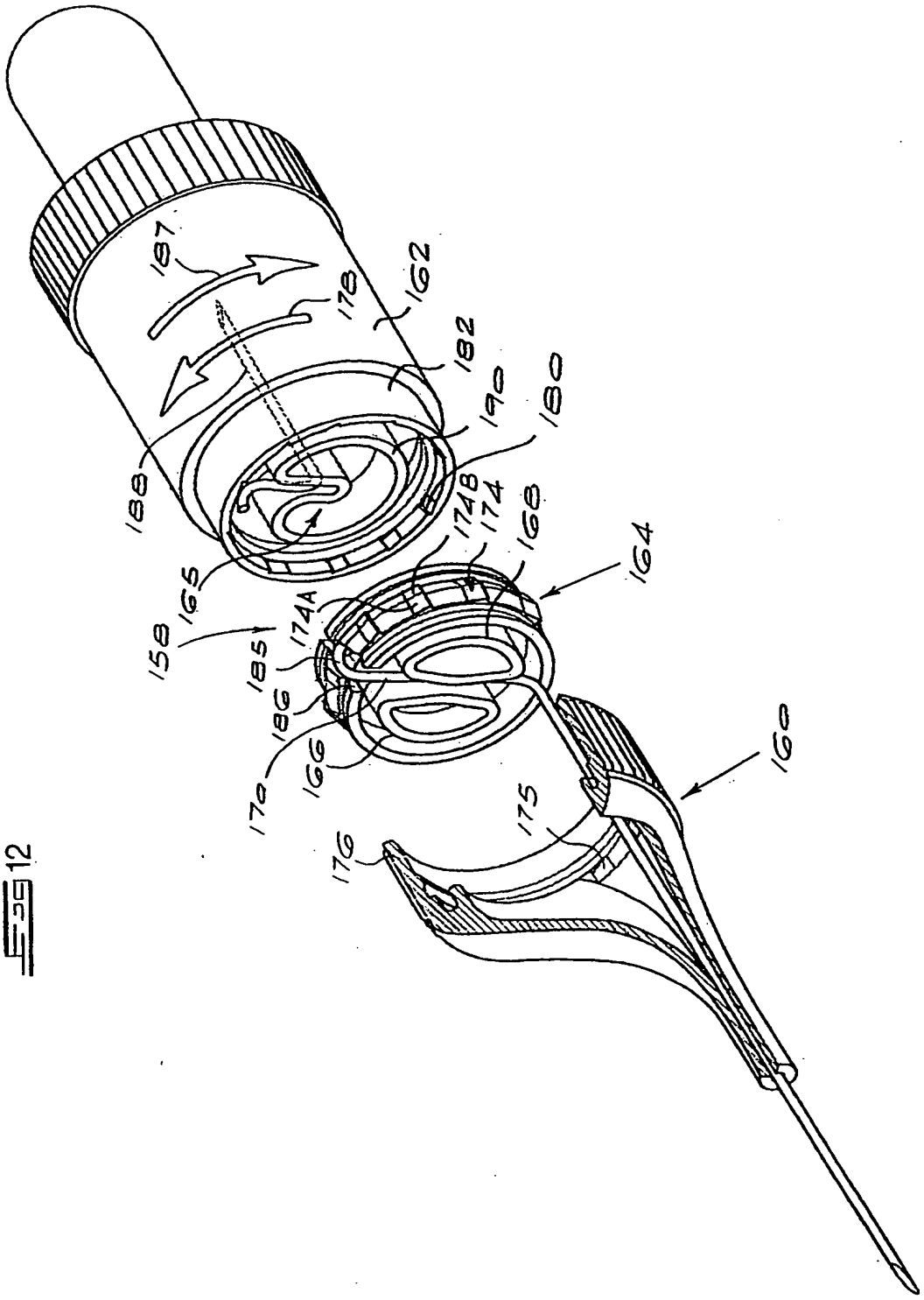

187
178
162
182
190
180
188
174B
174
168
164
165
158
174A
185
186
166
170
160
175
176

FIG 12

INTERNATIONAL SEARCH REPORT

International Application No
PCT/IB 00/00289

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61M5/46 A61M5/32

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 A61M

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 4 266 544 A (WARDLAW STEPHEN C) 12 May 1981 (1981-05-12) column 3, line 30 - line 58; figures 3-6	1
X	US 5 476 106 A (GARTZ KAJ) 19 December 1995 (1995-12-19) column 3, line 17 - line 54; figure 1	1-19
A	US 5 084 019 A (GARTZ KAJ) 28 January 1992 (1992-01-28) figures 5-8	1
A	US 4 582 257 A (SIEGLER FREDERICK) 15 April 1986 (1986-04-15) figures 8,9	1

-/--

[X] Further documents are listed in the continuation of box C.

[X] Patent family members are listed in annex.

* Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier document but published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
30 May 2000	09/06/2000

Name and mailing address of the ISA	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL - 2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	Ehrsam, F

Form PCT/ISA/210 (second sheet) (July 1992)

INTERNATIONAL SEARCH REPORT

Information on patent family members

Int. ational Application No
PCT/IB 00/00289

Patent document cited in search report		Publication date	Patent family member(s)		Publication date
US 4266544	A	12-05-1981	NONE		
US 5476106	A	19-12-1995	US	5084020 A	28-01-1992
			US	5084019 A	28-01-1992
			CA	2097329 A	31-05-1992
			WO	9209315 A	11-06-1992
US 5084019	A	28-01-1992	US	5084020 A	28-01-1992
			CA	2097329 A	31-05-1992
			WO	9209315 A	11-06-1992
			US	5476106 A	19-12-1995
US 4582257	A	15-04-1986	NONE		
US 4925450	A	15-05-1990	US	4784649 A	15-11-1988
			EP	0365632 A	02-05-1990
			JP	2504479 T	20-12-1990
			WO	8909072 A	05-10-1989
			AU	7857187 A	10-10-1988
			EP	0312545 A	26-04-1989
			JP	1502721 T	21-09-1989
			WO	8806900 A	22-09-1988
EP 0943351	A	22-09-1999	JP	11267210 A	05-10-1999

INTERNATIONAL SEARCH REPORT

Int. ational Application No
PCT/IB 00/00289

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication,where appropriate, of the relevant passages	Relevant to claim No.
A	US 4 925 450 A (BEUCHAT CHARLES E ET AL) 15 May 1990 (1990-05-15) figures 6,7	1
P,X	EP 0 943 351 A (MEDIKIT CO LTD) 22 September 1999 (1999-09-22) figures 2-5	1